**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC., ST. JUDE MEDICAL SYSTEMS AB, and ST. JUDE MEDICAL S.C., INC.,<br><br>Plaintiffs and Counterclaim Defendants,<br><br>v.<br><br>VOLCANO CORPORATION,<br><br>Defendant and Counterclaimant. | C. A. No. 10-00631-RGA-MPT<br><br>[redacted]<br><br>REDACTED PUBLIC VERSION |

**VOLCANO'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NO UNENFORCEABILITY FOR INEQUITABLE CONDUCT OR, IN THE ALTERNATIVE, FOR A RULING ON THE MERITS OF ST. JUDE'S UNENFORCEABILITY DEFENSE WITHOUT A HEARING**

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## I. INTRODUCTION

St. Jude cannot carry its clear and convincing burden, under the exacting standards of the Federal Circuit's *Therasense* case, of demonstrating that Volcano's '965 patent is unenforceable due to inequitable conduct. St. Jude does not contend that any inequitable conduct occurred during the prosecution of the '965 patent. Instead, it claims that inequitable conduct of two different types occurred in certain ancestor patents, which "infects" the '965 patent—but infectious unenforceability has ***never***, to Volcano's knowledge, been found after *Therasense*. To carry its heavy burden on the first theory, St. Jude must show that: (1) someone other than the named '965 inventors contributed novel ideas to its great-grandfather patent, the '827 patent; (2) that the '965 inventors knew of these contributions, knew they were inventive, and deliberately withheld them from the Patent Office with the specific intent to deceive the examiner; and (3) that this conduct was so egregious that it infected the '827 patent's great-grandchild, the '965 patent, which claims different subject matter. Under St. Jude's alternative theory, it must demonstrate that: (1) three medical journal articles concerning procedures for measuring intravascular pressure using fluid-filled or fiber-optic pressure sensors were material to—*i.e.,* would have precluded the patentability of—the '965 patent's parent application, the '327 patent; (2) that the '965 inventors knew these articles were material but deliberately withheld them with the specific intent to deceive the Patent Office; and (3) that this conduct was so egregious that it, too, infected the '327 patent's child application, the '965 patent, which claims different subject matter. St. Jude cannot establish any of these individual rungs, let alone the entire ladder it needs to prove inequitable conduct. Accordingly, Volcano respectfully requests that the Court enter summary judgment that the '965 patent is not unenforceable.

In the alternative, if the Court is disinclined to grant this motion at the present time, Volcano respectfully requests that the Court consider the evidentiary record, now complete, and

rule on St. Jude's unenforceability defense based on whatever additional written submissions the Court would like, rather than conduct a redundant and unnecessary evidentiary hearing. All of the relevant fact and expert witnesses have been deposed, and all relevant documents have been produced. An evidentiary hearing would not present the Court with any new information; it would instead serve only to rehash the various experts' reports and the rebuttal and impeachment brought out during their depositions. As set forth in detail below, Volcano respectfully submits that once briefing on the instant motion is concluded, the Court will have all of the information it needs to render a ruling on St. Jude's unenforceability defense.

## II. NATURE AND STAGE OF THE PROCEEDINGS

St. Jude filed its Joint Amended Answer and Counterclaims on April 13, 2012, asserting the affirmative defense of unenforceability of the '965 patent[1] based on inequitable conduct and seeking declaratory judgment of the same. [D.I. 188.] On October 21, 2012, St. Jude stipulated that its accused PressureWire 4 and PressureWire 5 products infringed Volcano's '965 patent.[2] [D.I. 434.] The Court provided Volcano with the opportunity to brief the issues as a summary judgment motion prior to ordering a hearing. [Trial 2 Tr. at 1055:2–21.]

## III. ARGUMENT

### A. Legal Standard

To prevail on a claim of inequitable conduct based on nondisclosure of allegedly material information, "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to

[1] The parties have agreed to dismiss without prejudice all other equitable defenses as moot in light of the juries' non-infringement findings.

[2] Volcano presented its infringement case against St. Jude's Certus and Aeris Generation 6 and 7 products to a jury on October 22–24, 2012. St. Jude did not present an invalidity case for Volcano's asserted patents. On October 25, the jury reached a verdict that the Certus and Aeris Generation 6 and 7 products did not infringe the asserted claims of the '965 patent. [D.I. 456.]

withhold it." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). "Because the party alleging inequitable conduct bears the burden of proof, the 'patentee need not offer any good faith explanation unless the accused infringer first … prove[s] a threshold level of intent to deceive by clear and convincing evidence.'" *Id.* at 1291 (quotations omitted). "An applicant's knowledge of a reference's materiality, however, cannot by itself prove, let alone clearly and convincingly prove, that any subsequent non-disclosure was based on a deliberate decision." *1st Media, LLC v. Electronic Arts, Inc.*, 694 F.3d 1367, 1375 (Fed. Cir. 2012) (reversing district court ruling of inequitable conduct due to insufficient evidence of intent). "Moreover, it is not enough to argue carelessness, lack of attention, poor docketing or cross-referencing, or anything else that might be considered negligent or even grossly negligent." *Id.* at 1374–75. An absence of specific intent to deceive "would effectively eviscerate *Therasense's* test for *mens rea* and reinflict the plague of patent unenforceability based on the thinnest of speculation regarding the applicant's putative mental state." *Id.* at 1375. "To meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Therasense*, 649 F.3d at 1290 (quotations omitted). "Indeed, the evidence must be sufficient to ***require*** a finding of deceitful intent in light of all the circumstances." *Id.* "When there are multiple reasonable inferences that may be drawn, intent to deceive ***cannot be found***." *Id.* at 1290–91 (emphasis added).

"[A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality." *Id.* at 1291. "When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc*., 651 F.3d 1318, 1334 (Fed. Cir. 2011) (quoting *Therasense* and vacating and remanding inequitable conduct finding in

light of *Therasense*). In the context of inventorship, "[a] good faith decision not to name a person as an inventor of a patent does not provide the basis for an inequitable conduct ruling." *Duhn Oil Tool, Inc. v. Cooper Cameron Corp.*, 818 F. Supp. 2d 1193, 1230 (E.D. Cal. 2011). "Because the issuance of a patent creates a presumption that the named inventors are the true and only inventors, the burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence." *Galderma Labs., L.P. v. Tolmar, Inc.*, CA 10-45-LPS, 2012 WL 4169686, at *52 (D. Del. Sept. 11, 2012) (quoting *Bd. of Educ. v. Am. BioSci, Inc.*, 333 F.3d 1330, 1337 (Fed. Cir. 2003)).

"[T]he taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family." *Therasense*, 649 F.3d at 1288. "However, the mere occurrence of inequitable conduct in connection with an application in a chain of applications is not sufficient to invalidate a patent issued as a result of a later application in that chain; instead, the earlier inequitable conduct in the chain must be related to the targeted claims of the ultimately issued patents sought to be enforced." *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 900 (N.D. Ill. 2006). "Inequitable conduct charges are disfavored by this court and charges of 'infectious inequitable conduct' even more so." *Eaton Corp. v. Parker-Hannifin Corp*., C.A. 00-751-SLR, 2003 WL 179992, at *1 (D. Del. Jan. 24, 2003). The relevant inquiry is whether the "inequitable conduct in prosecuting the [parent] patent had immediate and necessary relation to the ... enforcement of the [child] patents." *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 810–11 (Fed. Cir. 1990); *see also Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, CIV. 08-309-JJF-LPS, 2009 WL 4928024, at *9 (D. Del. Dec. 18, 2009) (allegations that "specifications are related and share some figures, that 'many of the claims of each patent include substantively the

same limitations,' and that all three patents have been asserted against the same [] products are not sufficient to establish the required 'immediate and necessary relation.'") This immediate and necessary relation must be shown by clear and convincing evidence. *Cordis Corp. v. Boston Scientific Corp.*, 641 F. Supp. 2d 353, 359 (D. Del. 2009).

### B. Prosecution of the '827 Patent Did Not Render the '965 Patent Unenforceable for Inequitable Conduct

St. Jude contends that the inventors of Volcano's '965 patent, Dr. Paul Douglas Corl, Robert Obara, and John Ortiz, committed inequitable conduct by deliberately withholding from the Patent Office alleged inventive contributions of Drs. Henry Allen and James Knutti to U.S. Patent No. 5,715,827 ("the '827 patent"), the great-grandparent of the '965 patent. In fact, as St. Jude's own expert conceded in deposition, neither Dr. Allen nor Dr. Knutti contributed anything inventive to the '827 patent; the '965 inventors did not submit a false declaration; there is ***no*** evidence, let alone clear and convincing evidence, that the inventors specifically intended to deceive the Patent Office; and any possible wrongdoing cannot carry over from the '827 patent to its very different great-grandchild, the '965 patent. Indeed, Volcano is not aware of ***any*** case—either pre- or post-*Therasense*—in which improper inventorship of an ancestor patent infected, and thereby rendered unenforceable, a child patent.

#### 1. The '827 patent inventors did not submit a false inventor declaration because they were the sole contributors of inventive ideas to that patent

It is undisputed that in 1993 and 1994, Dr. Corl, Mr. Obara, and Mr. Ortiz, the inventors of the '965 patent and its great-grandfather, the '827 patent, conceived of placing a microscopic solid-state pressure sensor on a guidewire to measure intravascular pressure.[3] Their invention of the WaveWire device marked the first time anyone had developed a piezoresistive pressure

[3] Ex. 1 (Obara lab notebook) at VOLC1467287–318; Ex. 2 (Obara Dep.) at 37–40; 55–57; 63–64); Ex. 3 (Corl Dep.) at 34–35).

sensor small enough to fit in a 0.018-inch guidewire, yet sensitive enough to be clinically useful. In developing WaveWire, the inventors enlisted Drs. Henry Allen and James Knutti of Silicon Microstructures Inc. ("SMI"), a chip manufacturing company, to fabricate the sensor chips for WaveWire.[4] (*See* Ex. 5[5] (5/27/11 Allen email) ("we were fabricators of the part").)

Among the earliest WaveWire-related patents was the '827 patent, which claims priority to September 2, 1994. Claim 1 of the '827 patent recites:

> 1. A guide wire having pressure sensing capabilities for measuring the pressure of liquid in a vessel comprising a flexible elongate member and having proximal and distal extremities and having an outside diameter of 0.018" or less, said distal extremity of said flexible elongate member being adapted to be disposed in the liquid in said vessel, a housing carried by the flexible elongate member and having a diameter substantially the same as the diameter of the flexible elongate member, said housing having a space therein, a pressure sensor mounted in the space in the housing, the pressure sensor comprising a crystal of semiconductor material having a well therein and ***forming a diaphragm having a thickness ranging from 2 to 5 microns***, said diaphragm being disposed in the housing in a manner so that it is sensitive to changes of pressure in the liquid in the vessel, said diaphragm being rectangular in shade and being bordered by a rim surrounding the well and formed of the crystal of semiconductor material, ***a backing plate formed of an insulating material bonded to the crystal and serving to reinforce the rim of the crystal of semiconductor material***, said backing plate having a cavity therein underlying the diaphragm and in substantial registration with the diaphragm with said cavity serving to provide a pressure reference, said crystal of semiconductor material having at least one diffused region therein formed of an impurity, said diffused region overlying the portion of the diaphragm where deflection will occur whereby upon the application of a pressure to the diaphragm a change in resistance will occur in the diffused region, conductive means carried by the crystal of semiconductor material and coupled to said at least one diffused region, a power source connected to the conductor means for supplying electrical energy to said at least one diffused region and means measuring the change in resistance in said at least one diffused region to ascertain the pressure being applied to the diaphragm by the liquid in the vessel, ***said crystal of semiconductor material having first and second sides, said well being formed so it extends through said one side together with troughs formed***

[redacted]

[5] All exhibits are attached to the Declaration of Thomas L. Halkowski in support of this motion.

> ***in the crystal of semiconductor material and opening on the opposite side of the crystal of semiconductor material***, conductive means including leads secured in said troughs and means in said troughs for establishing electrical connections between the leads in the troughs and the first and second diffused portions.

(Ex. 6 ('827 patent) at claim 1 (emphasis and coloring added).) St. Jude asserts that Drs. Allen and Knutti of SMI contributed inventive ideas to this claim, and has presented a declaration by Dr. Knutti and an expert report by Dr. Khalil Najafi purporting to establish Drs. Allen's and Knutti's inventorship. But at his deposition, Dr. Najafi conceded that each of the elements in the claim that Drs. Allen and Knutti supposedly invented was already known in the prior art.

Specifically, in his report, Dr. Najafi points to four elements of the '827 patent that were allegedly contributed by Drs. Knutti and Allen: choosing a piezoresistive instead of a capacitive sensor [Ex. 7 (Najafi Report) at ¶ 37]; using a Pyrex backplate to make a reference chamber [*id.* at ¶ 38 (blue emphasis above)]; designing the thickness and shape of the sensor diaphragm [*id.* at ¶¶ 39–40 (red emphasis above)]; and creating the troughs used to make the electrical connection to the sensor [*id.* at ¶ 41 (green emphasis above)]. But during his deposition, Dr. Najafi admitted that each of these elements was already known in the prior art. He conceded that the claimed piezoresistive diaphragm dimensions, including their thickness and shape, were known. (*See* Ex. 8 (Najafi Dep.) at 61:1–6 ("Q. MEMS pressure sensors having a diaphragm a few microns thick were known before 1994? A. Correct. Correct. MEMS diaphragms with -- MEMS pressure sensors with diaphragms a few microns thick were known before 19[94]."); 71:11–19 ("The impact of the size of the diaphragm, the thickness of the diaphragm, the width of the diaphragm, the shape of the diaphragm, on pressure sensitivity, all of those things were known by 1994; right? A. All of those had been studied and, yeah, generally known by 1994, for a range of dimensions or sizes of piezoresistive pressure sensors.") Dr. Najafi further acknowledged that using a Pyrex backplate to form a reference chamber was also known in the art. (*See id.* at

61:17–22 ("Q. And using a backing plate having a cavity to create a reference chamber for a MEMS pressure sensor, that was also known before 1994; right? A. So a backing plate having a cavity was also known."); 64:15–20 ("Q. Using Pyrex glass as a backing plate for a MEMS pressure sensor, that was known before 1994; right? A. Using Pyrex glass for MEMS pressure sensors as a backing plate was known before 1994, that's correct.")) Dr. Najafi additionally admitted that creating troughs in pressure sensors was known in the prior art. (*See id.* at 91:19–24 ("Q. Creating troughs in MEMS pressure sensors to attach electrical leads was also known by 1994; right? A. Troughs were used in a capacitive MEMS pressure sensor prior to 1994. That was developed at Michigan. So that was known.") Thus, Dr. Najafi, St. Jude's own expert, conceded at deposition that nothing Drs. Allen or Knutti contributed to the '827 invention was novel or inventive. Dr. Najafi's testimony was consistent with the expert report and testimony of Volcano's expert, Dr. Kensall Wise, who opined that "[t]he various aspects of the claimed pressure sensor component used in this inventive pressure-sensing guidewire were well known in the art prior to September 2, 1994." (Ex. 9 (Wise Report) at 3–4.)

Instead, Dr. Najafi testified that it was only the device "as a whole" that was novel, not any specific aspect, because "it fits within a very small diameter, and provides a specific performance." (Ex. 8 (Najafi Dep.) at 110:4–24.) However, it is undisputed that it was the actual '827 inventors, not Drs. Allen or Najafi, who conceived of the diameter of the device and dictated its performance standards. (*See, e.g.*, Ex. 3 (Corl Dep.) at 247:10–12 ("So our requirement was it had to be a certain size."); *id*. at 247:20–25 ("So they said, we will make a device to meet your size, using the technology that we have developed in-house."). Thus, St.

Jude's own expert agreed with Volcano's expert and the '827 inventors that neither Dr. Allen nor Dr. Knutti contributed any inventive ideas to the patent.[6]

The situation here closely resembles that of *Hess v. Advanced Cardiovascular Systems*, 106 F.3d 976 (Fed. Cir. 1997), where the Federal Circuit affirmed a finding that an engineer, Mr. Hess, had failed to establish he was a co-inventor of a patent on a cardiology catheter on which he consulted as a third party during development. In *Hess*, like here, when the actual inventors, Drs. Simpson and Robert, "first met with Mr. Hess, he was totally unfamiliar with angioplasty catheterization and the problems it involved. They explained to him what they were trying to do, and what difficulties they encountered." *Id.*[7] The Federal Circuit also found, like here, that "[t]he principles Mr. Hess explained to [the actual inventors] were well known and found in textbooks. Mr. Hess did no more than a skilled salesman would do in explaining how his employer's product could be used to meet a customer's requirements. The extensive research and development work that produced the catheter was done by Drs. Simpson and Robert." *Id.* at 981. Finally, the Court noted that "the patent has been outstanding for a considerable time and the patented device has been successful. In that situation, too, there is an equally strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention." *Id.* at 980. Here, despite the facts that the '827 patent issued in

[6] In fact, as Dr. Najafi conceded, the *only* inventive concept in the '827 patent was the combination of a solid-state pressure sensor with certain characteristics in a guide-wire smaller than 0.018 inches in diameter—a concept undisputedly contributed by the named inventors. [*See, e.g.*, Ex. 10 (Knutti Dep.) at 77:11–13 ("Cardiometrics presented the opportunity of a very small pressure sensor that…would be usable on the end of a guide-wire catheter."); 92:4–13; 98:10–15 ("I don't know who developed the guide wires."); 98:16–20 ("Q…SMI didn't come up with the guide wire. A. That's correct.").]

[7] Dr. Knutti repeatedly testified that Cardiometrics "presented the opportunity" of using a solid-state pressure-sensor on a guide wire, and that Cardiometrics, not SMI, developed the guide wire technology. [*See* Ex. 10 (Knutti Dep.) at 77:11–13; 92:4–13; 98:10–15; 98:16–20.]

1998 and that the WaveWire and its successor products have enjoyed significant success in the marketplace, Dr. Knutti did not come forward to assert his putative inventorship until St. Jude retained him in 2012, some 18–19 years after the conception in question.

Given these undisputed facts, the inventor declarations filed by Messrs. Corl, Obara, and Ortiz were not false as a matter of law, and St. Jude cannot meet its burden of proving false inventorship by clear and convincing evidence. *See Galderma Labs.*, 2012 WL 4169686, at *52 ("Inventorship requires a contribution that is beyond the exercise of ordinary skill in the art.").

**2. St. Jude cannot prove that the '827 inventor declaration was submitted with intent to deceive**

Even if, contrary to the undisputed evidence, St. Jude could prove by clear and convincing evidence that Drs. Allen and Knutti should have been included on the '827 patent as co-inventors, the "mere failure to name a co-inventor" does not render a patent unenforceable. *Intermec Techs. Corp. v. Palm Inc.*, 738 F. Supp. 2d 522, 563 (D. Del. 2010), *aff'd*, 466 F. App'x 881 (Fed. Cir. 2012). To rise to the level of inequitable conduct, St. Jude must prove, by clear and convincing evidence, that the named inventors had a specific intent to deceive the Patent Office. "To meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Therasense*, 649 F.3d at 1290. "Indeed, the evidence must be sufficient to ***require*** a finding of deceitful intent in the light of all the circumstances." *Id.* St. Jude has presented no evidence that can meet this extremely high burden.

Specifically, during his deposition, Dr. Corl testified that the chip design concepts recited in the great-grandparent of the asserted '965 patent—V-grooves, rectangular shape, and silicon backing—were commonly known at the time of the invention of the '827 patent. (*Compare* Ex.

6 ('827 patent) at claim 1 *with* Ex. 3 (9/27/11 Corl Dep.) at 249:4–9[8]; *id.* at 255:12–13 ("The desire for V grooves grew out of one of our requirements"); *id.* at 257:3–4 ("V grooves were a technology that was well known in the industry"); and *id.* at 253:24–254:9[9].) Because Dr. Corl understood these elements of the sensor element to have been known in the prior art, even if he were somehow mistaken, he cannot possibly have had the specific intent to deceive the Patent Office, nor can such intent plausibly be characterized as a reasonable inference, let alone "the single most reasonable inference," as required by *Therasense*.

Furthermore, Dr. Corl testified that the SMI engineers, one of whom candidly described their role as "fabricators of the part," manufactured the sensor chip to his and his co-inventors' specifications. (*See, e.g.*, Ex. 3 (Corl Dep. at 247:10–12 ("So our requirement was it had to be a certain size. And their -- their technology was that it would be piezoresistive."); *id*. at 247:20–25 ("it's not so much an idea they contributed. It's their technological capability that they had available to them. So they said, We will make a device to meet your size, using the technology that we have developed in-house.") Mr. Obara, Dr. Corl's coinventor, reinforced this testimony, stating at his deposition that Dr. Corl, not SMI, designed the sensor element used in the WaveWire. (*See* Ex. 2 (Obara Dep.) at 115:16–17 ("Doug Corl defined the design of the chip"), 119:1–14 (SMI was "manufacturing the chip for us" but "not solving design problems for us"), and at 133:20–24 ("I remember on the initial meeting Doug Corl standing in front of the board, whiteboard, and designing the design for [SMI personnel], explaining to them the principles of

[8] "That anodically bonded glass-to-silicone technology was a, you know, widely used technology that had been around for many years. They had used that technology back at Stanford. And the piezoresistive pressure sensor technology was well known and widely used."

[9] The rectangular sensor shape "was a suggestion on their part to meet our general requirement for maximum sensitivity. They said, well, within the constraints of wanting more sensitivity, we can either go thinner diaphragm or we can get a little bit by going longer. And ***that was our choice***. We figured make the diaphragm as thin as possible…and then get the extra sensitivity by adding the little bit of length, which hardly affected the overall dimensions of the device."

the design and so on. I vividly remember that.")) Because the '827 inventors believed that they, not Drs. Allen and Knutti, designed the claimed elements of the chip, even if these elements were themselves inventive, the named inventors cannot possibly have had the specific intent to deceive, nor can such intent, as a matter of law, reasonably be inferred.

Finally, for all the same reasons, there is ***no*** evidence, let alone clear and convincing evidence, that Messrs. Corl, Obara, or Ortiz committed "affirmative egregious misconduct" by submitting an "unmistakably false affidavit" to the Patent Office. *Therasense*, 649 F.3d at 1292. The only evidence of record on this point—the inventors' testimony, their laboratory notebooks, and the various prosecution histories—demonstrates the very opposite.

**3. The '827 patent conduct does not relate to the '965 patent**

Even if St. Jude could somehow prove by clear and convincing evidence that Drs. Allen and Knutti contributed inventive ideas to the '827 patent, that the inventor declarations filed for the '827 patent were false, and that the actual '827 inventors submitted their declarations with the specific intent to deceive the Patent Office, the ***'965 patent*** would still be enforceable because those declarations do not bear an "immediate and necessary relation" to the asserted '965 patent claims. *Consol. Aluminum*, 910 F.2d at 810–11. St. Jude claims that Dr. Knutti contributed various aspects of the sensor chip used in Volcano's original guidewires, and that some of these alleged contributions were improperly claimed in the '827 patent without proper inventorship attribution. However, neither St. Jude nor Dr. Knutti make any such claims about any features covered by the '965 patent, which relate to the physical structure of the guidewire and how the sensor chip is mounted therein. In fact, ***none*** of the features supposedly invented by Drs. Allen and Knutti—the choice of a piezoresistive sensor, the use of a Pyrex backing plate, the thickness of the sensor element, or V-shaped grooves—appears anywhere in the '965 patent

claims. Therefore, the alleged inequitable conduct does not relate to the targeted claims, and St. Jude cannot show infectious unenforceability. *Nilssen*, 440 F. Supp. 2d at 900.

Apparently conceding this point, St. Jude attempts to argue that the alleged '827 inequitable conduct is related to the '965 patent claims because the '965 patent relies on the '827 link in the prosecution chain in order to maintain its priority date.[10] Again, this contention falls far short of the level required to meet the very high standards required for infectious unenforceability. *Nilssen*, 440 F. Supp. 2d at 900; *see also Power Integrations*, 2009 WL 4928024, at *9 (no immediate and necessary relation despite fact that two patents' "specifications are related and share some figures" and that "many of the claims of each patent include substantively the same limitations"). Again, Volcano is not aware of ***any*** court, pre- or post-*Therasense*, that has found improper inventorship of a parent infected, and rendered unenforceable, a child patent.

Additionally, contrary to St. Jude's assertion (*see* Ex. 11 (Love Expert Report) at 38–39), there is nothing improper about tailoring claims in a continuation application to cover a competitor's products. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) (reversing district court ruling that patent was unenforceable for inequitable conduct; stating that "nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application"; and holding that such amendment does not "evidence deceitful intent.") So long as the newly amended claims are supported in the original specification—which the Patent Office found in the case of the '965 patent, *see, e.g.*, D.I. 329 at 18–22—the '965 claims

[10] *See* Ex. 11, the expert report inequitable conduct by John Love, St. Jude's patent law expert, at 33–39. The Court struck the parties' patent law expert reports, *see* D.I. 239, but Volcano encloses it with its brief solely as a point of reference for the Court.

properly claim priority to the original application and fall within the scope of what the named inventors invented and described, regardless of what Drs. Allen and Knutti did or did not contribute specifically to the claims of the '827 patent.

For all these reasons, St. Jude has failed as a matter of law to establish by clear and convincing evidence that the inventors specifically intended to deceive the Patent Office by filing false declarations that they were the sole inventors of the '827 patent, and that that conduct was so egregious that it infected and renders unenforceable the '965 patent.

### C. Prosecution of the '327 Patent Did Not Render the '965 Patent Unenforceable for Inequitable Conduct

St. Jude's alternative inequitable conduct theory is that one or more of the '965 inventors knew during the prosecution of U.S. Patent No. 6,767,327 ("the '327 patent"), which is a grandchild of the '827 patent and the parent of the '965 patent, that three medical journal articles were material to the patentability of the '327 patent, *i.e.*, that, had the Patent Office known about the articles, the '327 patent would not have issued; that the inventors deliberately withheld these articles with the specific intent to deceive the Patent Office; and that this deliberate withholding was so egregious that the child patent, the '965 patent, should be held unenforceable. But St. Jude has not presented clear and convincing evidence of any of these elements.

#### 1. The references cited by St. Jude are not material

The '327 patent is directed to several methods for using a solid-state pressure sensor and/or a flow sensor to measure pressure and flow characteristics on each side of a stenosis. St. Jude asserts that three medical journal articles, De Bruyne, De Bruyne II, and Di Mario, would have invalidated claims 10–14 of the '327 patent had they been disclosed to the Patent Office.[11] However, these journal articles discuss measuring pressure using fundamentally different kinds

[11] *See* Ex. 11 (Love Expert Report) at 14–22. St. Jude has not introduced any technical expert opinion about this alternative theory, and thus, it rests entirely on attorney argument.

of pressure sensors than what is claimed in the '327 patent and would have given no new relevant information to the patent examiner.

Independent claims 10 and 11 are reproduced below:

> 10. A method of measuring blood pressure proximally and distally of a stenosis in a vessel carrying blood, comprising the steps of:
> advancing a guide wire having a core wire extending from a proximal region to a distal region of the guide wire and ***carrying a solid state pressure sensor disposed on a distal region of the guide wire within the vessel*** to position the pressure sensor relative to the stenosis, and measuring blood pressure proximally and distally of the stenosis with the pressure sensor, wherein the blood pressure is measured by monitoring changes in a pair of ***resistive elements*** which respond oppositely to changes in pressure but are affected in a similar manner by changes in temperature.
> 11. A method of measuring blood pressure proximally and distally of a stenosis in a vessel carrying blood, comprising the steps of:
> introducing a guide wire ***carrying a first pressure sensor into the vessel***,
> ***introducing a catheter carrying a second pressure sensor into the vessel over the guide wire***,
> advancing the guide wire within the vessel to position the first sensor distally of the stenosis,
> advancing the catheter within the vessel to position the second sensor proximally of the stenosis,
> measuring blood pressure distally of the stenosis with the first sensor, and
> measuring blood pressure proximally of the stenosis with the second sensor.

(Ex. 12 ('327 patent) (emphasis added).)

The De Bruyne articles describe one way to measure the pressure gradient across a stenosis using a guiding catheter and fluid-filled guidewire that both transmit pressure through a column of fluid to pressure sensors located outside of the patient. (*See* Ex. 13 (De Bruyne) at 120; Ex. 14 (De Bruyne II) at 1015.) The De Bruyne articles cannot anticipate claims 10–14 of the '327 patent because the '327 patent claims require a pressure sensor mounted on the distal end of the guidewire itself, such that the sensor is physically carried inside the patient.[12]

[12] *See, e.g,* '327 patent, claim 10 ("advancing a guidewire . . . carrying a solid state pressure sensor disposed on the distal region of the guidewire"); claim 11 ("introducing a guide wire carrying a first pressure sensor into the vessel").

Furthermore, the De Bruyne references are not material for the purposes of inequitable conduct because they disclose nothing relevant to the '327 patent claims that was not already in front of the patent examiner. The fluid-filled guidewires used by De Bruyne "were developed by Advanced Cardiovascular Systems," (Ex. 13 (De Bruyne) at 120), and were disclosed in detail in U.S. Patent No. 4,953,553 to Tremulis, which was analyzed by the patent examiner during prosecution of the '327 patent. (*See* Ex. 15 ('327 file history), at, *e.g.*, 85–93 (02/11/2002 Office Action).) Tremulis discloses the method described by De Bruyne of using a fluid-filled, pressure-sensing guidewire together with a pressure-sensing catheter to measure the pressure gradient across a stenosis. (*See id*; Ex. 16 (Tremulis) at 1:56–61, 2:6–9, 4:18–38, 6:18–23.) Because De Bruyne merely rehashes what was taught by Tremulis, St. Jude cannot show by clear and convincing evidence that the De Bruyne references meet *Therasense*'s "but-for materiality" standard.

Di Mario describes yet another method, different from both the '327 patent and De Bruyne, of measuring the pressure gradient across a stenosis. Instead of using the solid-state piezoresistive pressure sensor described in the '327 patent, or the fluid-filled guidewire described by De Bruyne and Tremulis, Di Mario used a fiber optic system known as the Radi Pressure Guide. (*See* Ex. 17 (Di Mario) at 312.) Because Di Mario's disclosed method used an optical pressure sensor, this reference cannot anticipate claim 10, which calls for a "solid state pressure sensor" formed by "a pair of resistive elements." Nor can Di Mario anticipate claims 11–14 of the '327 patent. Claims 11–14 of the '327 patent require that the guidewire first be introduced into the artery or vessel, followed by "introducing a catheter carrying a second pressure sensor into the vessel over the guidewire." The procedure described by Di Mario is the opposite: first an "8F soft-tip Judkins guiding catheter" is introduced into the artery, after which the Pressure

Guide is introduced through the guiding catheter. (*See* Ex. 17 (Di Mario) at 311–12.) This difference is not incidental but was dictated by the technological choice of the fiber optic pressure sensor, which prevented the Pressure Guide from being detached from its control unit.[13] As it was physically impossible to introduce a catheter over the Pressure Guide, Di Mario and other Pressure Guide references cannot anticipate claims 11–14 of the '327 patent.

Furthermore, the Radi Pressure Guide itself was disclosed in another reference analyzed by the examiner, U.S. Patent No. 5,450,853 to Hastings. (*See* Ex. 20 (Hastings).) Hastings, like many other references discussed by the examiner,[14] discloses a "way of determining the severity of the occlusion" by measuring "pressure both proximal to and distal of the stenoses."[15] As Di Mario does not disclose anything regarding the '327 patent claims that was not already in front of the examiner, St. Jude cannot show by clear and convincing evidence that this reference is material. *Therasense*, 649 F.3d at 1291–92.

**2. St. Jude cannot demonstrate intent**

Even if the articles in question were material to patentability of the '327 patent, St. Jude cannot show that one or more of the inventors deliberately withheld them with the specific intent to deceive the Patent Office. St. Jude patches together snippets of Dr. Corl's deposition in an effort to show that he may have known about the articles. (*See* Ex. 3 (Corl Dep.) at 274:7–276:7.) But even if St. Jude could prove that Dr. Corl ***knew about*** these three references, St. Jude must then prove, again by clear and convincing evidence, that Dr. Corl made a deliberate

[13] *See* First Trial Tr. at 295:19–24 (Tenerz) ("Q. And would you agree that because it used a fiberoptic cable, it could not be detached at the proximal end for insertion of catheters or other equipment? A. We didn't succeed to do connectors. We tried, but we never succeeded."); *see also id.* at 399:15–400:20 (Popma); 501:7–502:12 (Smith); Second Trial Tr. 220:15–221:6 (Corl); 661:1–663:4 (Tenerz).

[14] *See, e.g.,* Ex. 18 (U.S. Pat. No. 4,928,693 to Goodin) at 1:12–22, 2:32–49, 4:11–29; Ex. 19 (U.S. Pat. No. 5,046,497 to Millar) at 9:37–46, 13:18–22; Ex. 16 (U.S. Pat. No. 4,953,553 to Tremulis) at 1:56–61, 2:6–9, 4:18–38, 6:18–23; Ex. 15 ('327 file history).

[15] Ex. 20 (Hastings) at 1:25–42; 7:66–8:7.

decision to ***withhold*** the references from the Patent Office with deceptive intent. *See Therasense*, 649 F.3d at 1290 ("[T]he specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.") The only evidence is to the contrary, as Dr. Corl's distinguished at his deposition between Radi's fiber-optic approach and the claimed invention:

> Q. Do you know if the fiberoptic Radi wire described here, do you know if that wire was used to measure FFR?
> A. I don't know, but I would speculate that it was since they measured in here. It's one of their two pressure-measurement technologies, besides catheters, which are subpar, so I speculate that they used it. And I know that they were desperate, Pijls and De Bruyne and their other colleagues were desperate to get any kind of pressure-measuring guidewire to pursue their research line. And at this time, it was very difficult to get pressure-measuring guidewires.

(Ex. 3 (Corl Dep.) at 285:20–286:8.) Dr. Corl further testified that "I'm not sure what the exact characteristics of this Radi fiberoptic device were, but I believe it had some of the properties of a guidewire, but not for ***real guidewire***." (*Id.* at 285:16–19 (emphasis added).) Thus, if Dr. Corl knew anything about Dr. De Bruyne's pre-1994 research, it was that he used Radi's optical Pressure Guide or some other "subpar" technology that did not qualify as a "real guidewire," *i.e.* a zero-profile wire onto which a catheter could be threaded. Thus, even if St. Jude could show that Dr. Corl was aware of these articles, noticed the doctors' passing reference to Radi's fiber-optic-based pressure sensor, and then diligently followed up to read these articles in detail, St. Jude ***still*** could not prove intent to deceive because the method of measuring intravascular pressure using that fiber optic system differed fundamentally from the new method invented by Dr. Corl and others at Cardiometrics using their solid-state, catheter-over-guidewire pressure-sensing system. Neither Dr. Corl nor his co-inventors claim to have invented FFR itself or methods for performing FFR with a fluid-filled or optical pressure sensor, and thus they could not as a matter of law have had the specific intent to deceptively withhold information relating to

such concepts or use. Intentional deception is not as a matter of law a reasonable inference here, let alone the single most reasonable inference. *Therasense*, 649 F.3d at 1290.

**3. Any inequitable conduct from the '327 patent is not related to the '965 patent claims**

Finally, even if—contrary to the facts—St. Jude could prove inequitable conduct by clear and convincing evidence for the '327 patent based on the alleged intentional, deceptive withholding of these three references, that conduct could not infect the '965 patent because, as with the '827 patent, it bears no "immediate and necessary relation" to the '965 patent claims. *Consol. Aluminum*, 910 F.2d at 810–11. The articles St. Jude accuses Dr. Corl of withholding relate to clinical methods of diagnosing the severity of a stenosis. The '965 patent relates to the structure of a novel pressure-sensing guidewire, including a sensor housing with certain features, two coils, and a solid state pressure sensor mounted in a particular way. Thus, the difference between the two sets of claims here is even more profound than with respect to the '827 patent.

St. Jude does not appear to contest that the claims of the '965 are unrelated to the subject matter of the allegedly withheld references. Instead, St. Jude again returns to its argument that rendering the '327 patent unenforceable would have disrupted the chain of continuation applications resulting in issuance of the '965 patent. As explained in detail above, this argument lacks merit, and summary judgment of no infectious unenforceability is warranted.

## IV. IN THE ALTERNATIVE, THE COURT SHOULD DECIDE THE ISSUE ON THE PAPERS, WITHOUT A HEARING

If the Court is not inclined to grant Volcano's summary judgment motion, Volcano respectfully requests that the Court alternatively decide the issue on whatever additional paper submissions the Court deems necessary, without an evidentiary hearing. The evidentiary record is both closed and complete, containing numerous fact and expert deposition transcripts, expert reports, and numerous key documents—including laboratory notebooks, articles, and prosecution

histories—all of which have been included in connection with this brief, and on the basis of which, along with the briefing on the instant motion, the Court can conclusively determine any remaining disputed factual issues. Conversely, conducting an evidentiary hearing with numerous live witnesses will unnecessarily tax the parties' and the Court's resources without revealing any new information. St. Jude has indicated it would present live testimony from three witnesses, namely, Dr. Knutti, Dr. Najafi, and Dr. Menachem Nassi. Volcano may want to present live testimony from four live witnesses, namely, the three '965 inventors, Dr. Corl, Mr. Ortiz, and Mr. Obara, as well as its expert, Dr. Wise. All of these witnesses have been already been deposed—some twice—and it is highly unlikely that an evidentiary hearing would furnish the Court with any new information not already contained in the various laboratory notebooks, file histories, declarations, reports, and deposition transcripts. Instead, each witness would testify on direct examination consistently with his expert report or declaration, while he would be impeached on cross-examination with his admissions during deposition. The parties' own arguments would simply track those presented during the briefing on the instant motion. This exercise in futility is unlikely to enlighten the Court, but it is certain to consume the Court's, and the parties', time, energy and resources. Thus, Volcano requests that the Court consider and decide the issues on the copious evidentiary record already before it.

## V. CONCLUSION

For all the reasons set forth above, Volcano respectfully requests that the Court grant Volcano's motion for summary judgment of no unenforceability for inequitable conduct or, in the alternative, for a ruling on the merits of St. Jude's unenforceability defense without a hearing.

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